

**REMARKS**

**Summary Of The Office Action & Formalities**

**Status of Claims**

Claims 1-9 are pending in the application. By this amendment, Applicant is amending claim 3. No new matter is added.

**Additional Fees**

Submitted herewith is a Petition for Extension of Time with fee.

**Preliminary Matters**

Applicant thanks the Examiner for acknowledging the claim to foreign priority and for confirming that certified copies of the priority documents were received.

Applicant also thanks the Examiner for considering the references listed on forms PTO/SB/08 submitted with the Information Disclosure Statements filed on January 3, 2006.

Claim 3 is being amended to recite “specific gravity.” This amendment is being made to conform claim 3 with the specification. (See Current Application, U.S. Pub. No. 2007/0152821, ¶ [0023].)

**Art Rejections**

Claims 1-9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Caja Lopez et al. (U.S. Pub. No. 2001/0001176) in view of Platt (U.S. Pat. No. 5,937,789).

**Claim Rejections Under 35 U.S.C. § 103(a)**

In rejecting claims 1-9 over Caja Lopez in view of Platt, the grounds of rejection state:

Cala Lopez et al discloses a capsule located in a stomach of an animal. Caja Lopez et al teaches that in prior art devices, that it is well known to use a capsule having a length of about 75mm and a diameter of about 18 mm and have a device whose density

exceeds 2 g/cm<sup>3</sup> (paragraph 0003). The Caja Lopez et al device, specifically, has a density of “not less than 3.5 g/cm<sup>3</sup>” and a weight of 65-60 g, length of 69 mm and a diameter of 20 mm (see Table 1 and paragraph 0023). While Caja Lopez et al does teach a density of not less than 3.5 g/cm<sup>3</sup>, which would include being equal to or greater than 4 g/cm<sup>3</sup>, Caja Lopez et al does not specifically teach a density equal to or greater than 4 g/cm<sup>3</sup> or a specific gravity equal to or greater than 3. Platt discloses a similar capsule and teaches that the body should have a density of at least 3 g/cm<sup>3</sup> and a specific gravity of at least 4. Platt further discloses that the density needs to be sufficiently high so that the incidence of rejection may be minimized and that is well known to use a material including zirconium oxide (which would inherently have a density equal to or greater than 4 g/cm<sup>3</sup>) (see abstract and column 2, line 48- column 3, line 3). Therefore a modification of Caja Lopez et al such that the material used is a zirconium oxide would have been obvious in view of the teachings of Platt which show that it is well known to use such a material with a capsule in order to provide the desired density and specific gravity to maintain the device in the animal.

Office Action at page 2-3. Applicant respectfully traverses.

Regarding claim 1, Applicant respectfully submits that claim 1 is not obvious over Caja Lopez in view of Platt because (1) Platt teaches away from using the type of bolus disclosed in Caja Lopez; and (2) neither reference discloses the combination of values of total and effective weight, dimensions, composition, and specific weight that is recited in claim 1.

(1) Platt Teaches Away From Using Ceramic Boluses

One skilled in the art would not have combined Caja Lopez with Platt because Platt teaches away from using the type of bolus disclosed in Caja Lopez. Platt states that “[o]ne disadvantage of the ceramic capsules is that they are relatively time-consuming and costly to manufacture.” As a consequence, Platt teaches that “[t]he [bolus] comprises a substantially solid body formed from a *plastics* material which is filled with a material having a desired density.”

(Platt, col. 2, lines 36-38, *emphasis added.*) Therefore, one skilled in the art would not have combined the plastic bolus in Platt with the ceramic bolus in Caja Lopez.

(2) Neither Caja Lopez nor Platt Disclose the Combination of Features of Claim 1

The object of the inventions in Caja Lopez and Platt was to provide a high density bolus enabling small dimensions to be used, and as a consequence, make it possible to fix the bolus reliably in the reticulum of the ruminant. (*See for example*, Caja Lopez, [0010]; Platt, col. 1, lines 56-60.)

The solution to the problem presented in Caja Lopez was to increase the specific weight to achieve boluses that were smaller than the prior art boluses. Thus, the main object of the invention in Caja Lopez was to increase the total density of the material that constitutes the body of the capsule by using alumina and silica, which have very high densities. (*See* Caja Lopez, [0014]).

Similarly, Platt states that “*the presence of [a] filler enables the device to have sufficiently high density so that the incidence of rejection may be minimised.*” (*See* Platt, col. 2, lines 49-51.) Platt further states that “*the desired density of the filler may be selected on the basis of the specific gravity*” (Platt, col. 2, lines 55-56) and that “*the device is sized and shaped to allow it to be administered easily.*” (Platt, col. 2, lines 32-33).

As such, in both Caja Lopez and Platt, the smaller dimensions of the bolus are a result of the choice of components that impart very high density. Thus, the size of the boluses are a consequence of the very high density, not a requirement. Neither Caja Lopez nor Platt describe that the dimensions of the bolus are a critical factor in retaining the bolus in the stomach of the ruminant. In no way does Platt or Caja Lopez disclose that a very high density *and* very small dimensions enable fixing the bolus reliably in the reticulum of the ruminant. Rather, Platt

discloses that “the devices are preferably sized to be compatible with known dosage apparatus” to allow for easy administration to the animal. (Platt, col. 2, lines 32-36.) Thus, the length is never considered in Platt as playing a role in the retention of the bolus in the stomach of ruminants. Nor does Caja Lopez disclose or suggest that the length of the capsule is a critical parameter for retaining the bolus in the stomach of the ruminant. (*See generally* Caja Lopez.) Therefore, even if Platt and Caja Lopez were combined, they would not disclose the critical parameters recited in claim 1.

At the filing date of the present application, it was not known that it was important not only to increase the specific weight of the body of the capsule, but also to increase its length. As such, an important feature of the claimed subject matter lies with “*the length of the capsule, more than in the weight itself.*” For example, “*The investigations carried out by the authors of the present invention make it clear that when the length of the capsule increases the chances of passing through the reticulo-omasal orifice are reduced.*” (See Current Application at U.S. Pub. No. 2007/0152821, ¶ [0018]).

While the total weight of the capsule should be high enough for the animal not to regurgitate it, it should be borne in mind that the high weight facilitates the passage of the capsule towards subsequent sections of the digestive apparatus, with the capsule eventually being lost through defecation. (See Current Application, U.S. Pub. No. 2007/0152821, ¶ [0017]). Applicant determined that the “length of the capsule, more than the weight itself, is a critical factor for controlling it as it passes through the reticulo-omasal orifice and for avoiding the resulting movement towards subsequent sections of the digestive system.” (See Current Application, U.S. Pub. No. 2007/0152821, ¶ [0018]).

In summary, the claimed subject matter provides capsules not only with a specific gravity and a total weight both high enough, but also with a length high enough so that the capsule can be maintained in the stomach of ruminants. “With the *combination* of the values of total and effective weight, dimensions, composition and specific weight, a suitable weight of the capsule is achieved in order that it is not regurgitated.” (Current Application, U.S. Pub. No. 2007/0152821, ¶ [0041]). Thus, the claimed subject matter enables one skilled in the art to obtain a large variety of capsules with appropriate configuration parameters adapted to each animal at any age or weight. This means that capsules with a large variety of dimensions with optimal retention percentages (100%) can be produced. As shown with the equations that explain the retention (see U.S. Pub. No. 2007/0152821, ¶ [0048]), the present invention is easily applicable to each size of animal, even for new-born animals. These equations make it possible to estimate the retention percentage expected in the reticulo-rumen of animals based on the dimensions of the capsule, which makes it possible to determine the optimum dimensions of the capsule to be used in practice.

Therefore, the issue is not whether a skilled person could have arrived at the present invention by modifying Caja Lopez in view of Platt, but whether one would have done so, taking into account the teachings of Caja Lopez in view of Platt. Accordingly, Applicant respectfully submits that the present invention is not taught or suggested in the prior art, and thus requests that the Examiner withdraw the rejection of claim 1.

Regarding claim 2, this claims recites that “the ceramic material of the body (2) comprises zirconium oxide (ZrO<sub>2</sub>).” The Examiner relies on Caja Lopez as disclosing a ceramic bolus and Platt as disclosing the use of zirconium oxide. As discussed above, however, Platt teaches away from the use of a ceramic bolus, since ceramic boluses are “relatively time-

consuming and costly to manufacture." (Platt, col. 1, lines 31-32.) Therefore, one skilled in the art would not have combined the teachings of Platt with Caja Lopez.

Regarding claim 8, this claim recites "an elastic element (5), arranged in at least one of the rounded ends of the body (2) and secured by a bracket (6) of biodegradable material." Neither Caja Lopez nor Platt disclose the use of any type of bracket on the capsule. As such, Applicant respectfully submits that claim 8 is allowable over the cited prior art.

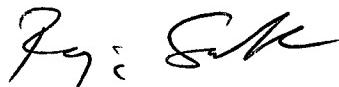
Regarding claims 2-9, these claims depend from independent claim 1. As such, Applicant submits that claims 2-9 are allowable at least by virtue of their dependency from claim 1.

**Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



---

Raja N. Saliba  
Registration No. 43,078

SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON OFFICE  
23373  
CUSTOMER NUMBER

Date: October 27, 2008